In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-740V

SYLVIA ROWE, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: July 14, 2023

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Alexa Roggenkamp, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLMENT[1]

On June 22, 2020, Sylvia Rowe filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges a Table injury - that she suffered a shoulder injury related to vaccine administration ("SIRVA") after receiving a Tetanus Diphtheria acellular-Pertussis ("Tdap") vaccine in her right deltoid on September 26, 2018. Petition at 1; Ex. 16 at 1.[3]

[1] Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] Petitioner also filed a separate, second, Petition on August 28, 2020, alleging that she suffered a left-sided SIRVA as a result of an influenza vaccination administered into her left deltoid on September 26, 2018 (at the same appointment at which she received the Tdap vaccination implicated in the instant case (*see* Ex. 2 at 35)). That claim was informally settled between the parties, and I issued a Decision, pursuant

The case was assigned to the Special Processing Unit of the Office of Special Masters ("SPU").

After a full review of the evidence, I find it most likely that Petitioner received her September 26, 2018 Tdap vaccination in her right deltoid or shoulder, has satisfied all Table requirements for a right-sided SIRVA injury, and is otherwise entitled to compensation for her right-sided SIRVA.

I. Relevant Procedural History

After the case's initiation and SPU assignment, Respondent filed a Rule 4 Report recommending that entitlement to compensation be denied under the terms of the Vaccine Act. ECF No. 30. Specifically, Respondent argued that the vaccination record indicates that Petitioner received her September 26, 2018 Tdap vaccination in her left shoulder. ECF No. 29 at 6-7 (citing Pet. Ex. 1).

I therefore set deadlines for the filing of briefs addressing Petitioner's entitlement to compensation. ECF No. 32. On November 29, 2021, Petitioner filed a Motion for Ruling on Record in support of this claim. ECF No. 34. On December 13, 2021, Respondent filed an opposition brief arguing that right shoulder situs had not been established, and therefore Petitioner could not demonstrate that her pain and reduced range of motion are limited to the shoulder in which her intramuscular vaccine was administered. ECF No. 35 at 5-6 (citing 42 C.F.R. § 100.3(c)(10)(iii)). This matter is ripe for my resolution.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See* Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to

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to the parties' Stipulation, awarding Petitioner compensation on January 27, 2022. *Rowe v. Sec'y of Health & Hum. Servs.*, No. 20-1093V, 2022 WL 624045 (Fed. Cl. Jan. 27, 2022)

be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[4] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a Tdap vaccine. 42 C.F. R. § 100.3(a)(I)(C). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged

[4] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. Section 11(c)(1)(A)(B)(D)(E).

signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time-frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g.* NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

III. Relevant Factual Evidence

I have reviewed all evidence filed to date, but limit my discussion below to those items most relevant to the disputed situs question. 42 C.F.R. § 100.3(c)(10)(iii). Based upon a review of the entire record, including all medical records, declarations, and additional evidence filed, I find that Petitioner's September 26, 2018 Tdap vaccine was, more likely than not, administered in her right deltoid. I base my finding on the following evidence:

A. Records

- On September 26, 2018, Petitioner was seen by Dr. Andrea Ferrantino, MD, of Clinton Medical Associates in Rochester, New York for an annual physical examination. Ex. 2 at 28. At this appointment, Petitioner received both flu and Tdap vaccines. Ex. 2 at 33, 35. The records corresponding to that visit document that Petitioner was vaccinated at this time, but do not provide any additional information regarding the vaccinations (situs, vaccination lot number, *etc.*). *Id.*

- A separate record from Clinton Medical Associates provides more detailed information regarding Petitioner's September 26, 2018 Tdap vaccination. That record indicates that the "site" of Petitioner's September 26, 2018 Tdap vaccination was her "LD" or left deltoid. Ex. 1 at 2. The record is entirely electronic, or computer generated.[5]

[5] A similar record was filed in Petitioner's left-sided SIRVA claim indicating that Petitioner's flu vaccination was also administered in her left deltoid. *Rowe v. Sec'y of Health & Hum. Servs.*, No. 20-1093V, Ex.1. Petitioner attempted to obtain a vaccine consent form in relation to her September 26, 2018 Tdap vaccination, but none was produced. Ex. 11. A consent form related to Petitioner's September 26, 2018 flu

- The next day, Petitioner emailed Dr. Ferrantino and reported that she "had a bad reaction to the tet[a]nus and Flu vaccine[s] I was given yesterday. I was up all night with severe pain in my right arm (tet[a]nus) and chills, nausea, cold sweats . . . the pain in my arm kept me up all night." Ex. 9 at 1; Ex. 15 at 1. Dr. Ferrantino responded to Petitioner's email indicating that she was "[s]orry to hear [Petitioner] had such a bad reaction to [her] immunizations yesterday," and noted that the "tetanus shot can cause some soreness in the arm, but usually not such a systemic reaction." *Id.* Petitioner was advised to notify Dr. Ferrantino if she did "not continue to improve." Ex. 9 at 1.

- On October 1, 2018 (five days after her vaccinations), Petitioner was seen again by Dr. Ferrantino for "a chief complaint of right upper arm [pain]." Ex. 2 at 25. The medical record indicates that Petitioner "received [a] Tdap [vaccine] in *right arm* last week." *Id*. (emphasis added). The record further states that Petitioner had "a lot of discomfort in her right arm" the night of her vaccination and "since then she has had a persistent soreness in her right arm and difficulty with range of motion of her right arm and right shoulder because of the pain." *Id.* at 25-26. An examination of Petitioner's right shoulder demonstrated reduced range of motion, tenderness and pain." *Id*. at 26. Dr. Ferrantino assessed Petitioner with "right upper arm/shoulder pain following TDAP Vaccine 1 week ago." *Id.* at 27.

- On October 8, 2018, Petitioner sought care from an orthopedic provider, Karilynn M. Cervini, NP (nurse practitioner), at the University of Rochester Medical Center for a chief complaint of right shoulder pain. Ex. 3 at 20. Petitioner reported "that she received a tetanus injection about 2 weeks ago and has had ongoing pain since." *Id.* Petitioner was assessed with "right shoulder rotator cuff tendonitis, bursitis, impingement." *Id.* at 21.

- On October 10, 2018, Petitioner underwent an initial evaluation for physical therapy for her right shoulder. Petitioner reported her right shoulder pain "follow[ed] a tetanus shot in R[ight] arm." Ex. 4 at 17.

- On October 15, 2018, Petitioner was seen at Clinton Medical Associates by Gregory W. Rosinski, PA, for bilateral shoulder pain. Ex. 2 at 20. The medical record provided a history of Petitioner's treatment with Dr. Ferrantino on October 1, 2018, for right shoulder pain following a "Tdap vaccine one week prior to the right shoulder and the flu influneza vaccination at the left shoulder." *Id.* Petitioner

vaccination was obtained and filed, however, that record contained no information regarding the site of vaccination. Ex. 10 at 8.

reported to Mr. Rosinski that the "left shoulder was actually sore at the time of her initial visit; however there was quite a bit more discomfort in the right shoulder so the focus was there." *Id.*

- On October 23, 2018, Petitioner was again by her orthopedics provider, Ms. Cervini, "for further evaluation of her right shoulder." Ex. 3 at 44. Ms. Cervini provided a history that Petitioner was being seen "about 4 weeks after receiving a tetanus injection into her right shoulder that caused her discomfort. She also reports today that she has noticed pain in her left shoulder, she also received an injection in that shoulder 4 weeks ago." *Id.*

B. Declaration

Petitioner executed a signed and sworn declaration on November 23, 2021 addressing her September 26, 2018 Tdap and flu vaccinations. Ex. 16. In regard to the administration of her vaccinations, Petitioner states:

> I received the Tdap vaccine in my right shoulder, and the influenza vaccine in my left shoulder. I specifically requested that each vaccine be given in a different arm. I thought it made more sense to do it that way because I figured it would ease the soreness, rather than having one arm get a shot twice. I clarified that I had received the tetanus in the right arm when I contacted my doctor via a MYCHART message the following day which was September 27, 2018.

Ex. 16, ¶ 3.

IV. Findings of Fact

The only disputed factor in this case is whether Ms. Rowe received her Tdap vaccination in her right shoulder, and therefore her "[p]ain and reduced range of motion are limited to the [right] shoulder in which the intramuscular [Tdap] vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii).

Respondent argues that the vaccination record which indicates Petitioner received both her Tdap and flu vaccinations in her "LD," resolves this issue since that record "explicitly" provides that the Tdap vaccine was administered in Petitioner's left shoulder. ECF No. 35 at 6. Although this contention has merit, it is overcome by a review of the record in its totality.

As a preliminary matter, Petitioner's vaccination record, relied upon by Respondent, is entirely electronic, increasing the probability for error in regard to whether a vaccination was administered in the "RD" or "LD," in contrast to vaccine administration records where the site is handwritten or circled on the record itself.[6]

As observed in other SIRVA cases, it is not unusual for the information maintained on computerized forms regarding site of vaccination to be incorrect. *See*, *e.g.*, *Desai v. Sec'y of Health & Human Servs.*, No. 14-811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); *Rodgers v. Sec'y of Health & Human Servs.,* No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); *Stoliker v. Sec'y of Health & Human Servs.*, No. 17-0990V, 2018 WL 6718629, at *3-6 (Fed. Cl. Spec. Mstr. Nov. 9, 2018). Thus, although such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply because they come first – and in fact the nature of their creation provides some basis for not accepting them at face value, absent persuasive evidence that they reflect a treater's agency in identifying situs.

Additionally, Petitioner's declaration provides a reasonable explanation for why she received her Tdap vaccination in her right shoulder. As noted above, she was to receive two vaccines on September 26, 2018, and "I specifically requested that each vaccine be given in a different arm. I thought it made more sense to do it that way because I figured it would ease the soreness, rather than having one arm get a shot twice." Ex. 16, ¶ 3. This is a logical and persuasive reason for why both vaccines would not likely have been administered in the same arm.

There is also the fact of what was reported and recorded in numerous subsequent records. As discussed in other decisions, consistent reporting to treating physicians that a shoulder injury was associated with a vaccination received in the same shoulder can serve as probative evidence sufficient to overcome a contradictory vaccination record. *See e.g.*, *Desai,* 2020 WL 4919777, at *13-14; *Mogavero v. Sec'y of Health & Human Servs.*, No. 18-1197V, 2020 WL 4198762, at *3 (Fed. Cl. Spec. Mstr. May 12, 2020); *Hanna v. Sec'y of Health & Human Servs.*, No. 18-1455V, 2021 WL 3486248, at *9-10 (Fed. Cl. Spec. Mstr. July 15, 2021); *Mezzacapo v. Sec'y of Health & Human Servs.*, No. 18-1977V, 2021 WL 1940435, at *7 (Fed. Cl. Spec. Mstr. Apr. 19, 2021).

[6] The case offered by Respondent to support his position that the contemporaneous vaccine record provides the most persuasive evidence – in contrast to later contemporaneous treatment records – involved both an electronic medical record *and a handwritten log* providing the same description of the injection site. *Schmidt v. Sec'y of Health & Hum. Servs*., No. 17-1530V, 2021 WL 5226494, at *3, 8 (Fed. Cl. Oct. 7, 2021). As I explained in *Schmidt,* situs records that require specific action on the part of the vaccine administrator, such as manually circling the situs or manually hand-writing the situs, are more reliable than computerized or electronic records. *Id.*, at *8-9.

In this case, beginning the day following her vaccine, Petitioner emailed her primary care provider and reported a reaction to her vaccines. In addition to suffering a more systemic, if transient, reaction, that she apparently attributed to both vaccinations, she complained of pain in her right arm from the tetanus vaccine. Ex. 9 at 1; Ex. 15 at 1. (Petitioner reported in her email "severe pain in my right arm (tetnus) [sic] and chills, nausea, cold sweats"). Five days after, Petitioner was seen by her primary care provider with a chief complaint of right shoulder pain, and the history in that record provides Petitioner "received [a] Tdap [vaccine] in *right arm* last week" and "that evening" she "noted feeling a lot of discomfort in her right arm." *Id*. (emphasis added). Ex. 2 at 25. Again, on October 10, 2018, Petitioner reported her shoulder pain "follow[ed] a tetanus shot in R[ight] arm." Ex. 4 at 17. Taken as a whole, [7] Petitioner's contemporaneous treatment records in the weeks following her vaccinations preponderantly demonstrate that she most likely received her September 26, 2018 Tdap vaccine in her right shoulder.[8]

In light of this finding, I also find Petitioner has satisfied the third SIRVA QAI criterion and established her "[p]ain and reduced range of motion [from her Tdap vaccination] are limited to the [right] shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii).

V. Other Table Requirements and Entitlement

Petitioner has established all other requirements for a Table SIRVA claim. There is no history of shoulder pain, inflammation, or dysfunction that would explain the post-

[7] I note that in his Rule 4 Report, Respondent points in passing to a record from an orthopedics encounter on May 23, 2019, stating that Petitioner's *left* shoulder adhesive capsulitis "appears to be a traumatic onset associated with an injection of tetanus and flu shots." Ex. 3 at 124-125. However, I note that this same record from May 23, 2019 (approximately eight months after Petitioner's vaccinations) also describes symptoms in both Petitioner's left and right shoulder, noting that the pain in her left shoulder was greater than the pain in her right shoulder (at that time), and specifically indicates "[o]nset of symptoms are specific to 09/26/2018, at which time she had a flu shot and tetanus shots in the *shoulders*" – implying she received a vaccination in each of her shoulders. *Id.* at 124 (emphasis added). Additionally, an earlier treatment record from this same provider (University of Rochester – Orthopedics), less than a month following her vaccinations, documents a history of Petitioner's right shoulder pain being associated with her tetanus vaccination in the right shoulder. Ex. 3 at 44.

[8] In cases where I have determined that a petitioner provided sufficient evidence to rebut the site of administration listed in the vaccine record, the medical records demonstrated consistent and multiple reports of pain attributed to the vaccination alleged as being administered in the injured shoulder, along with efforts to obtain treatment close in time to vaccination. *See, e.g.*, *Gallo v. Sec'y of Health & Human Servs.*, No. 18-1298V, 2019 WL 7496617, at *3-4 (Fed. Cl. Spec. Mstr. Dec. 5, 2019); *Rodgers v. Sec'y of Health & Human Servs.*, No. 18-0559V, 2020 WL 1870268, at *3-4 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); *cf. Marion v. Sec'y of Health & Human Servs.*, No. 19-0495V, 2020 WL 7054414, at *9 (Fed. Cl. Spec. Mstr. Oct. 27, 2020) (Petitioner failed to rebut the site of administration listed on the vaccine record when he did not complain of pain in the allegedly injured shoulder until more than six months after vaccination, did not attribute his shoulder pain to the vaccine until an additional three months thereafter, and sought medical treatment for other conditions during the first six months after vaccination without mention of shoulder pain).

vaccination injury. 42 C.F.R. § 100.3(c)(10)(i). Her pain began within 48 hours after vaccination. 42 C.F.R. §§ 100.3(a)(I)(C), (c)(10)(ii). There is not preponderant evidence of another condition that would explain the symptoms. 42 C.F.R. § 100.3(c)(10)(iv). However, even if a petitioner has satisfied the requirements of a Table injury or established causation-in-fact, he or she must also provide preponderant evidence of the additional requirements of Section 11(c), *i.e.*, receipt of a covered vaccine, residual effects of injury lasting six months, *etc*. *See generally* § 11(c)(1)(A)(B)(D)(E). But those elements are established or undisputed in this claim. I therefore find that Petitioner is entitled to compensation in this case.

Conclusion

Based on the entire record, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation. A Damages Order will issue.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master